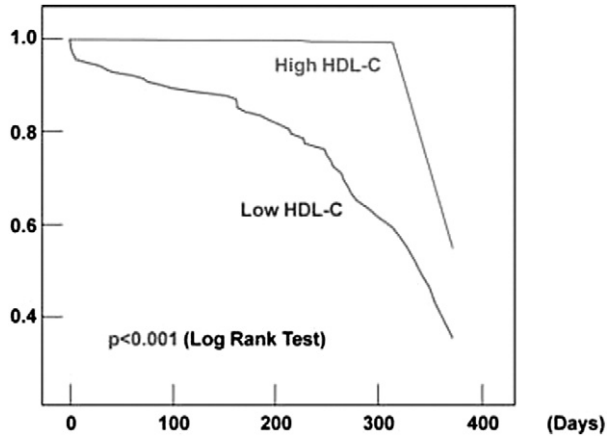

Conclusions: Independent of low-density lipoprotein-cholesterol, HDL-C was associated with better 1-year outcome in patients with ACS underwent elective PCI.

Stent Fracture and Longitudinal Deformation

Hall D

Tuesday, October 23, 2012, 8:00 AM–10:00 AM

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TCT-534

Longitudinal Stent Deformation: Insights On Mechanisms, Treatments and Outcomes From The Food And Drug Administration Manufacturer And User Facility Device Experience Database

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Background: Longitudinal stent deformation (LSD) is a recently described complication of PCI but mechanisms contributing to its occurrence and associated clinical outcomes remain unclear. The FDA Manufacturer and User Facility Device Experience (MAUDE) database is a voluntary international electronic reporting system whose aim is to capture major adverse events involving medical devices. We sought to identify cases of LSD reported to this database to gain insight into procedural and anatomical factors that predispose to this complication and associated clinical outcomes.
Methods: The MAUDE database was searched from 1992 until 31st October 2011 using 11 defined search terms. Individual reports identified using this search strategy were studied for the presence of longitudinal stent deformation, defined as the distortion or shortening of a stent in the longitudinal axis following successful stent deployment.
Results: 57 unique cases of LSD were identified between 2004-2011. A significant increase in the reporting of LSD in the last two years was observed with most reported cases in stents based on the Element platform (90%). The lesions in which LSD was reported were complex (vessel calcification 26%; tortuosity 25%; long 28%; ostial disease 21%) and most frequently occurred following attempts to pass or withdraw secondary devices through a previously deployed stent (89% cases where mechanism identified). The majority of cases required further treatment (79%) with further stent deployment performed in 58% cases and balloon post-dilatation alone performed in 18% cases. Adverse clinical outcomes including emergent cardiac surgery and acute and sub-acute stent thrombosis occurred in 8 cases.
Conclusions: LSD is reported most commonly in cases of complex angiographic disease. This complication can occur secondary to a variety of mechanisms and identification and treatment is important, since adverse incidents such as emergent CABG and stent thrombosis may occur. The recent increased reporting of this complication appears to be related to the introduction of the Element stent platform. A novel classification system is proposed to facilitate future reporting of this complication.

TCT-535

Abstract Withdrawn

TCT-536

Biomechanical assessment of the longitudinal compression behavior of drug eluting coronary stents: an in vitro comparative study

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Background: Significant longitudinal compression has been clinically observed in cases where drug-eluting coronary stents were crossed by other interventional devices. Our objective was to characterize stent longitudinal resistance under simulated clinical worst case crossing scenarios in good apposition and malapposition in-vitro models.
Methods: 6 commercially available coronary balloon-expandable stent designs were evaluated. First direct parallel plates longitudinal crush resistance was conducted after deploying 3 samples/design to 3 mm diameter. Then 12 samples/design were tracked over a 0.014″ interventional guidewire, positioned and deployed in either good apposition or malapposition coronary vessel models, 6 samples each, respectively. After deployment and withdrawal of the balloon, a new balloon was advanced over the guidewire automatically using the IDTE 2000 (Interventional Device Testing Equipment, Machine Solutions, Inc, Flagstaff, AZ, USA). For each sample, the force required to track the balloon through the stent and the change in stent length after balloon crossing were both calculated.
Results: In the parallel plate crush test, 3 out of 6 stent designs demonstrated higher longitudinal crush rates compared to the Resolute, Medtronic, Minneapolis USA (Promus Element, Boston Scientific Corp., Natik USA & Coroflex Blue, BBraun, Melsungen Germany, $p<0.001$; Orsiro, Biotronik, Berlin Germany, $p=0.038$). In the simulated use test, longitudinal crush ranged from 5 to 22%; however, no statistically significant differences in longitudinal crush were seen between stent types for both good apposition ($p=0.836$) and malapposition cases ($p=0.447$). One stent type showed significantly higher longitudinal crush ($p=0.027$) in the malapposed model compared to the good apposition model.
Conclusions: Lower resistance to pure mechanical longitudinal crush of some stent designs seen in bench testing did not correlate to significantly higher crush rates in good simulated clinical conditions. Nevertheless, it would be useful to take account the rough mechanical characteristics of some new stents to minimize longitudinal compression during stent implantation.

TCT-537

Abstract Withdrawn

TCT-538

Predictors of Stent Fracture and Impact on Neointimal Proliferation: Experimental Insights into the Mechanisms of Drug Eluting Stent Failure

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Background: Stent fracture (SF) has been frequently reported in clinical trials and it has been associated with restenosis and thrombosis. In this study we aimed to determine the predictors of stent fracture by using a single stent design in the porcine coronary model.
Methods: A total of 113 Cypher stents were implanted in normal coronary arteries at a 10% overstretch ratio in a single (81.4%), overlapping (30.6%) or T-bifurcation (19.4%) stent configuration. At termination, we reviewed high-contrast film–based radiographs to examine for the presence of SF. SF was graded as minor (<2 SF), multiple (≥2 SF) and major (multiple SF with complete transection or SF at multiple sites). Angiographic and histo-morphometric data were compared between groups with SF and without SF (non-SF).
Results: SF was found in 11 stents (9.5%; minor = 3(27.3%), multiple = 3(27.3%), and major = 5(45.5%)). SF was more commonly seen in longer stents (SF= 19.9±4.8 mm versus non-SF= 14.3±3.2 mm, $p<0.001$), T-bifurcation location (SF: 68.8% versus non-SF: 10.9%, $p<0.001$) and overlapping stents (SF: 75.0% versus non-SF: 22.8%, $p<0.001$). Angiographic restenosis (>50%) was higher in the SF (33.3%) group compared to non-SF (4.3%, $p=0.016$) and it was found only on the multiple (1 of 3) or major (2 of 5) SF groups. The presence of SF was associated with a greater degree of histologically derived neointimal proliferation (neointimal area= SF: 3.42±2.63 mm^2 versus non-SF: 2.62±1.79 mm^2 and % area stenosis= SF: 43.1±19.5% versus non-SF: 36.6±20.6%). T-bifurcation location (OR [95%CI] = 80.81[9.42, 693.52], $p<0.001$) and stent overlapping (OR [95%CI] = 46.18[5.44, 391.72], $p<0.001$) were identified as independent predictors of SF.
Conclusions: At the experimental setting, the incidence of SF found was high. Specific technical situations (i.e., overlapping stents) were predictors of SF and were associated to higher degrees of neointimal proliferation. SF may be a strong contributor of stent failure in complex technical situations.

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